Xiamen Acurio Instruments Co., Ltd
Angel Liu
General Manager Assistant
3rd-4th Floors, BI Park, No.2028
Wengjiao West Road, Haicang District
Xiamen, 361026 Cn

Re: K180685
Trade/Device Name: AS-3XX Series Fingertip Pulse Oximeter (with models AS-301, AS-302, AS-301-L, AS-302-L, AS-303, AS-304, AS-304-L, AS-311)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: October 19, 2018
Received: October 25, 2018

Dear Angel Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180685

Device Name
The AS-3XX Series Fingertip Pulse Oximeter (with models AS-301, AS-302, AS-301-L, AS-302-L, AS-303, AS-304, AS-304-L and AS-311)

Indications for Use *(Describe)*
The AS-3XX Series Fingertip Pulse Oximeter (with models AS-301, AS-302, AS-301-L, AS-302-L, AS-303, AS-304, AS-304-L and AS-311) is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult in hospitals, hospital-type facilities, and home environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

AS-3XX Series Fingertip Pulse Oximeter

510(k) Number: K180685

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.87(h) and 21 CFR 807.92.

Submitter:

Xiamen Acurio Instruments Co., Ltd
3rd-4th Floors, Biomedical Industry Park, No.2028, Wengjiao West Road, Haicang District, Xiamen, Fujian, 361026, CHINA

- **Contact Person:**

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- **Date Prepared:**

November 28, 2018

Name of the Devices:

- **Device Common Name**: Oximeter
- **Device Proprietary Name**: AS-3XX Series Fingertip Pulse Oximeter (with models AS-301, AS-302, AS-301-L, AS-302-L, AS-303, AS-304, AS-304-L, AS-311)
- **Classification Name:** Oximeter
- **Classification:** Class Ⅱ
- **Regulation Number:** 21CFR 870.2700
- **Product Code:** DQA

- **Review Panel:** Anesthesiology

Legally Marketed Predicate Device(s):

K140582 Fingertip Pulse Oximeter, Model JPD-500

Indications for Use:

The AS-3XX Series Fingertip Pulse Oximeter (with models AS-301, AS-302, AS-301-L, AS-302-L, AS-303, AS-304, AS-304-L and AS-311) is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult in hospitals, hospital-type facilities, and home environments.

Device Description:

The AS-301/AS-302/AS-301-L/AS-302-L/AS-303/AS-304/AS-304-L/AS-311 Fingertip Pulse Oximeter manufactured by ACURIO provides noninvasive blood oxygen measurement by the dual-wavelength spectrophotometric technique, and shows the results by the OLED. The oximeter is easy to operate, small in volume, light in weight, convenient in carrying, low consumption in design and with strong resistance to ambient light interference. 2pcs of AAA batteries can be continuously used for 20 hours, and the battery voltage can be indicated. The fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adults in hospitals, hospital-type facilities, and home environments.

The components of the oximeter include the body part and a hanging rope.

Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different spectra absorption of hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger), to a receiver on the other side. Two beams of different wavelength of lights (660nm red and 895nm near infrared light) can be focused onto a human nail tip through c clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

Comparison to Predicate Devices:

The Substantial Equivalence Comparison Chat is provided as follows:

Table1: Substantial Equivalence Comparison Chart

510(K) Summary

Comparison items	Manufacturer (aCurio)		Manufacturer (Jumper)	Comparison results
Name	Fingertip pulse oximeter		Fingertip pulse oximeter	Identical
Model	AS-301/AS-302/AS-301-L/AS-302-L/AS-303/AS-304/AS-304-L/AS-311		JPD-500A	——
510(K) number	K180685		K140582	——
Regulatory Class	Class Ⅱ		Class Ⅱ	Identical
Intended use	This product is used for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adults.		This product is used for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult and pediatric users.	Identical
Indications for use	The AS-3XX Series Fingertip Pulse Oximeter (with models AS-301, AS-302, AS-301-L, AS-302-L, AS-303, AS-304, AS-304-L and AS-311) is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult in hospitals, hospital-type facilities, and home environments.		The JPD-500A Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The portable fingertip device is indicated for adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care, etc)	Similar
Target population	Adults only		Adult and pediatric users	Similar
Anatomical sites	Fingertip		Fingertip	Identical
Where used	hospitals, hospital-type facilities, and home environments.		Home and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc.	similar
Energy used and/or delivered	D.C.3.0V (2×AAA alkaline batteries)		D.C. 3.0V (2×AAA alkaline batteries)	Identical
Human factors				
Design	Body part and a lanyard		Body part and a lanyard	Identical
Performance	Measuring principle	Dual-wavelength spectrophotometry	Dual-wavelength spectrophotometry	Identical

	Measurement range	AS-301/AS302/AS303 AS-304/AS-311: SpO2: 36% ~ 99% Pulse rate: 30bpm ~ 250bpm	SpO2: 35% ~ 100% Pulse Rate: 25bpm ~ 250bpm	Similar
		AS-301-L/AS302-L: SpO2: 36% ~ 100% Pulse rate: 30bpm ~ 250bpm		
	Measurement accuracy	AS-301/AS-302/AS-303/AS-304/AS-311: SpO2: ±3% (70% - 99%), ±3% (70% - 80%), ±2% （80% - 90%)，±2%（90% - 99%) less than 70% no definition Pulse rate accuracy : ±2bpm	SpO2: ±2% (70% ~100%), no definition (35%~69%) Pulse rate: ±2bpm	Similar
		AS-301-L/AS-302-L/AS-304-L: SpO2: ±3% (70% - 100%) ±3% (70% - 80%), ±2% （80% - 90%)，±2%（90% - 99%) less than 70% no definition Pulse rate accuracy : ±2bpm		
	Low perfusion	SpO_2 and pulse rate can be	Measurement performance in low perfusion condition is	Similar

	error	shown correctly when pulse-filling ratio is 0.2%	0.3%.	
	Light sensor	RED wavelength 660nm IR wavelength 940nm	RED wavelength 660nm IR wavelength 940nm	Identical
	Protection against electric shock	Internal power supply; Type BF	Internal power supply; Type BF	Identical
	Operating environment	Operation temperature: 5-40℃ Relative humidity: 15% - 95 %(Non condensing)	Operation temperature: 5-40℃ Relative humidity: 15% - 80 %(Non condensing)	Similar
	Storage environment	Storage temperature: -20~55℃ Relative humidity: 15% - 95 %(Non condensing)	Storage temperature: -10°C~50°C Relative humidity: 10% - 95 %(Non condensing)	Similar
	Weight	50g (including batteries)	57g (including batteries)	Similar
	Size	AS-301, AS-301-L: 56(L)×34(W)×32(H)mm	64(L)×35(W)×34(H) mm	Similar
		AS-302, AS-302-L: 58(L)×35(W)×32(H)mm		
		AS-303: 57(L)×35(W)×37(H)mm		
Standards met	ISO 80601-2-61: 2011 IEC 60601-1: 2005 IEC 60601-1-2: 2007/AC		ISO 80601-2-61: 2011 IEC 60601-1: 2005 IEC 60601-1-2: 2007/AC	Identical

	ISO 10993-5: 2009 ISO 10993-10: 2010 ISO 13485: 2003 ISO 15223-1: 2012 IEC 62304: 2006 IEC 62366: 2007 ISO 10993-1: 2009/AC: 2010 IEC 60601-1-11: 2010 IEC 60601-1-6: 2010	ISO 10993-5: 2009 ISO 10993-10: 2010 ISO 13485: 2003 ISO 15223-1: 2012 IEC 62304: 2006 IEC 62366: 2007 ISO 10993-1: 2009/AC: 2010 IEC 60601-1-11: 2010 IEC 60601-1-6: 2010	
Materials	ABS+TPR	ABS+TPR	Conform to the bio-compatibility requirements.
Biocompatibility	Passed the detection of ISO10993-5 and ISO10993-10.	Passed the detection of ISO10993-5 and ISO10993-10.	Conform to the bio-compatibility requirements.
Compatibility with the environment and other devices	The pulse oximeter can't be used in an MRI or CT environment, in situations where alarms are required, or in an explosive atmosphere.	The pulse oximeter can't be used in an MRI or CT environment, in situations where alarms are required, or in an explosive atmosphere.	Identical
Sterility	Non-sterile	Non-sterile	Identical
Electrical safety	Same	Same	Identical

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

The Sponsor performed a risk assessment based on the changes made to their predicate device and determined that the following non-clinical testing was necessary to demonstrate that the changes did not introduce any new risks to the subject device.

Laboratory testing was conducted to validate and verify that the Pulse Oximeters continued to meet all requirements of related international standards, including electrical safety, EMC, software, bio-compatibility. Results of these tests demonstrated compliance to the requirements of the below consensus standards and FDA Guidance documents.

Electrical Safety and Performance： *1. IEC 60601-1:2005+A1:2012；* *2. ISO 80601-2-61:2011.*
Medical Electrical Equipment and medical Electrical Systems Used in the Home

Healthcare Environment: *1. IEC 60601-1-11:2010+CORR.1:2011.*
Electromagnetic Compatibility: *1. IEC 60601-1-2:2007.*
Biocompatibility: *1. ISO 10993-5:2009* *2. ISO 10993-10:2010*
Software: *1. IEC 62304: 2006* *2. General Principles of Software Validation – Final Guidance for Industry and FDA Staff.*
Pulse Oimeters Guidance: *Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff*

Therefore, we conclude that the AS-3XX Series Fingertip Pulse Oximeter (with models AS-301, AS-302, AS-301-L, AS-302-L, AS-303, AS-304, AS-304-L, AS-311) is both safe and effective for its intended use.

Discussion of Clinical Tests Performed:

Clinical hypoxia accuracy testing (controlled desaturation study) was conducted during induced hypoxia studies on 10 healthy, nonsmoking, light-to-dark-skinned subjects in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO2) of the proposed device was compared with arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a CO-oximeter. The accuracy of the device is in comparison with the CO-oximeter samples measured over the SpO2 range of 70-100%.

Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, the result showed that the error is far less than the scope specified in the STANDARD ; and the Agreement between Methods of Measurement with Multiple Observations per each subject was analyzed with the Bland and Altman statistics, the analysis demonstrated that the vast majority of data is within ±95% limit of agreement, the data points beyond or below this scope were regarded as outliers. By analyzing, these few outliers are occasional, which does not raise safety and performance concerns regarding the accuracy of the device.

Conclusions:

The AS-3XX Series Fingertip Pulse Oximeter(with models AS-301, AS-302, AS-301-L, AS-302-L, AS-303, AS-304, AS-304-L, AS-311) has the same intended use and

similar characteristics as the predicate device. Moreover, bench testing contained in this submission demonstrates that any difference in their technological characteristics do not raise any different questions of safety or effectiveness. Thus, the AS-3XX Series Fingertip Pulse Oximeter (with models AS-301, AS-302, AS-301-L, AS-302-L, AS-303, AS-304, AS-304-L, AS-311) is substantially equivalent to the predicate devices.